

REMARKS

Claims 1-50 are currently pending in the application. Claims 1, 36, 39, 42, 48 and 50 have been amended. Support for the amendment to claims 1, 39, 48, and 50 is found throughout the specification and the figures, for example, on at least page 13, line 26. Support for the amendment to claims 36 and 42 is found throughout the specification and the figures. Applicants respectfully assert that no new matter has been added and request reconsideration of the claims currently pending in the application.

Applicants note the Examiner's attachment regarding Applicants' submission of informal drawings with the application. Formal drawings are being submitted herewith.

On page 3 of the Office Action, claims 1-6, 9-11, 13, 15-16, 18-19, 21, 23, 26, and 39 are rejected under 35 U.S.C. §102 (b) as being anticipated by Duran (U.S. Patent No. 5,545,215). Applicants respectfully traverse the rejections.

The Examiner states that Duran discloses a prosthesis (figure 9) comprising a reinforcement element (20) and a prosthetic conduit (28) of biocompatible material having a cylindrical section and an expanded section with the reinforcement at the junction therebetween.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain

a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Duran does not teach every element of claims 1-6, 9-11, 13, 15-16, 18-19, 21, 23, 26, and 39, and therefore fails to anticipate claims 1-6, 9-11, 13, 15-16, 18-19, 21, 23, 26, and 39.

Duran relates to an external frame or stent that is sutured to a valved conduit. See abstract. The stent is placed so that it fits exactly with the bulges or sinuses of Valsalva of the conduit. See col. 8, lines 8-11.

Claim 1 states that the prosthetic conduit has a generally cylindrical section and an expanded section extending from an end of the generally cylindrical section. . The expanded section in Duran does not extend from an end of the generally cylindrical section. Rather, stent 20 is in the middle of the conduit. Since Duran does not disclose every element of the claimed invention, Duran does not anticipate claim 1.

The Examiner states that in claim 39, a portion of the reinforcement element 20 is attached downstream from the valve. Claim 39 sets forth a prosthesis that includes a reinforcement element and a prosthetic conduit. The reinforcement element is circumferentially attached towards one end of the prosthetic conduit. The reinforcement element, or stent 20, in Duran does not extend towards one end of the prosthetic conduit. Rather, stent 20 is in the middle of the conduit. Since Duran does not disclose every element of the claimed invention, Duran does not anticipate claim 39.

Dependent claims 2-6, 9-11, 13, 15-16, 18-19, 21, 23, and 26 which are dependent from independent claim 1, were also rejected under 35 U.S.C. §102(b) as being anticipated by Duran. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims

include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-6, 9-11, 13, 15-16, 18-19, 21, 23, and 26 are also in condition for allowance. Applicants respectfully request withdrawal of the rejection of claims 1-6, 9-11, 13, 15-16, 18-19, 21, 23, 26, and 39 under 35 U.S.C. §102 (b) as being anticipated by Duran.

On page 4 of the Office Action, claims 1, 7-8, 10-13, 15, 17, 21-22, 26-34, 36, and 38-50 are rejected under 35 U.S.C. §102 (e) as being anticipated by Thubrikar, et al. Applicants respectfully traverse the rejections.

The Examiner states that Thubrikar et al discloses a prosthesis (figs. 3 and 15) comprising a reinforcement element (31-33, the seam) and a prosthetic conduit (22) of biocompatible material having a cylindrical section and an expanded section with the reinforcement element at the junction therebetween.

As stated above, to anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Thubrikar et al does not teach every element of claims 1, 7-8, 10-13, 15, 17,

21-22, 26-34, 36, and 38-50, and therefore fails to anticipate claims 1, 7-8, 10-13, 15, 17, 21-22, 26-34, 36, and 38-50.

Thubrikar sets forth an aortic root prosthesis that includes a tube 20. The separate sinuses 30 are attached to the proximal end 21 of tube 20 by stitching the sinus edge 35 of each sinus to the scalloped edge at proximal end 21. See col. 9, lines 6-12. The Examiner considers the reinforcement element to be the seam formed at 31-33.

Applicants state in claim 1 that the reinforcement element is circumferentially positioned at the junction between the generally cylindrical section and the expanded section. As shown in Figures 3 and 15 of Thubrikar, the reinforcement element is not circumferentially positioned at the junction between the generally cylindrical section and the expanded section. Rather, the reinforcement element (seam) is placed at different positions around the tube. Thus, the reinforcement element is not circumferentially positioned at the junction between the generally cylindrical section and the expanded section. Since Thubrikar does not disclose every element of the claimed invention, Thubrikar does not anticipate claim 1.

Similarly, in claims 39, 48, and 50 the reinforcement element is circumferentially attached to the prosthetic conduit. As discussed above, this is not shown in Thubrikar. Since Thubrikar does not disclose every element of the claimed invention, Thubrikar does not anticipate claims 39, 48 and 50.

Claim 30 sets forth that the expanded section includes tubules connecting the central lumen of the expanded section to an external opening. In Figure 14 of Thubrikar, the expanded section includes holes 80 and 81. The coronary ostium and coronary arteries are then sutured to the sinus 30. See col. 11, lines 25-30. The Thubrikar conduit

does not have tubules. Since Thubrikar does not disclose every element of the claimed invention, Thubrikar does not anticipate claim 30.

Claim 36 pertains to a prosthesis comprising a generally cylindrical section and an integral expanded section connected to the generally cylindrical section. The expanded section in Figure 12 of Thubrikar includes three separate sinuses which are attached to the conduit. The expanded section is not integral.

Similarly, claim 42 relates to a prosthesis having a first prosthetic conduit section and a second integral prosthetic conduit section. Figures 16 and 17 in Thubrikar do not disclose a second integral prosthetic conduit section. Instead, Thubrikar shows separate sinuses attached to the conduit. Since Thubrikar does not disclose every element of the claimed invention, Thubrikar does not anticipate claims 36 and 42.

Dependent claims 7-8, 10-13, 15, 17, 21-22, 26-29, 31-34, 38, 40-41, 43-47, and 49 which are dependent from independent claims 1, 30, 36, 39, 42, and 48 were also rejected under 35 U.S.C. §102(e) as being anticipated by Thubrikar. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1, 30, 36, 39, 42, and 48. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 7-8, 10-13, 15, 17, 21-22, 26-29, 31-34, 38, 40-41, 43-47, and 49 are also in condition for allowance. Applicants respectfully request withdrawal of claims 1, 7-8, 10-13, 15, 17, 21-22, 26-34, 36, and 38-50 under 35 U.S.C. §102 (e) as being anticipated by Thubrikar, et al.

On page 6 of the Office Action, claims 35 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Duran in view of Thubrikar, et al. Applicants respectfully traverse the rejections.

The Examiner states that Duran is silent as to whether tubules are connected to the expanded section, and that Thubrikar discloses another prosthesis including tubules connected to the expanded section to attach the coronary arteries. Col. 6, lines 60-62.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations.

Claim 30 states that the expanded section has tubules. Duran does not include tubules. Thubrikar fails to remedy the deficiencies of Duran. As discussed above, in Figure 14 of Thubrikar, the expanded section includes holes 80 and 81. The coronary ostium and coronary arteries are then sutured to the sinus 30. See col. 11, lines 25-30. The Thubrikar conduit does not have tubules. For at least these reasons, Applicants submit that the proposed combination of references does not disclose every limitation set forth in claim 30. Claim 35 is dependent from claim 30. It is believed that the rejection of claim 35 is moot in view of the remarks made in connection with independent claim 30.

Claim 37 is dependent from claim 36. Neither claim 36 nor claim 37 includes the tubule limitation. Applicants are not able to respond to this rejection since Applicants do not understand it. Applicants request further clarification of this rejection.

On page 6 of the Office Action, claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Duran in view of Lapeyre, et al. (U.S. Patent No. 6,068,657). Applicants respectfully traverse the rejection.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations.

The limitations of claim 1 are not met by Duran since Duran does not have an expanded section extending from an end of the generally cylindrical section. Lapeyre does not remedy the deficiencies of Duran since Lapeyre is a prosthetic valve. . For at least these reasons, Applicants submit that the proposed combination of references does not disclose every limitation set forth in claim 1. Claim 14 is dependent from claim 1. It is believed that the rejection of claim 14 is moot in view of the remarks made in connection with independent claim 1.

Applicants respectfully request withdrawal of the rejection of claims 35 and 37 under 35 U.S.C. § 103(a) as being unpatentable over Duran in view of Thubrikar, et al.

Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Duran in view of Lapeyre, et al.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

Altera Law Group, LLC
Customer Number 22865

Date: November 17, 2003

By: Hallie A. Finucane
Hallie A. Finucane
Reg. No. 33,172
HAF/mar